China allows cloning

China released on January 16 its first written regulation that allows therapeutic cloning. 'Guidelines for research on human embryonic stem cells,' which was jointly released by the Ministry of Science and Technology (MST, Beijing) and the Ministry of Health (Beijing), prohibits any research on human reproductive cloning, but allows therapeutic cloning subject to strict conditions. According to the regulation, the stem cells used for research can be obtained either from spare embryos from *in vitro* fertilization or from naturally aborted embryos, with the informed consent of the donor. The regulation specifically forbids the trade of human gametes, germ cells and embryos. The rules also prohibit the implantation of the product of the fusion of two separate human embryos into reproductive systems of human beings or animals. Wang Yu, deputy director of the Department of Agriculture and Society under the MST, says the regulation will help fuel the development of China's biotechnologies. The policy will also enable China to clarify its stance in the United Nation's (New York) imminent vote on a proposed treaty outlawing human cloning, which was postponed to October 2004. *HJ*

First beer marketed for its GM content

Since January 29, Swedes have been able to purchase a new beer derived from genetically modified (GM) maize. Launched by the microbrewery Österlenbryggarna (Ystad, Sweden), the beer project was initiated by Monsanto (St. Louis, MO, USA) and received support from other multinational agricultural biotechnology firms, which will monitor the sales of GM beer in the run-up to April 18. From that date, all products derived from or containing GM ingredients or organisms will be subject to new EU labeling rules (*Nat. Biotechnol.* **21**, 6, 2003). Launching the product in Sweden gives the industry an opportunity to gauge the reactions of a market that is regarded as being the most positively disposed toward biotechnology in Europe, according to the last Eurobarometer opinion poll. Swedes view GM foods as the least favorable application of biotechnology, but that opposition is softening, says Bjorn Fjaestad, adjunct professor of science communication at Mid-Sweden University (Östersund), who was involved in analyzing the Swedish data for the Eurobarometer survey. "We used to be among the most negative in the mid-1990s, long before the question of GM food had even reached Britain," he says. "But that has changed. Over the years, the opposition against GM food has grown very much in southern Europe." *CS*

Acambis cans UK research

Vaccines firm Acambis (London) announced on January 30 that it will dump or sell off three projects that were expected to give poor returns on investments: vaccines for travelers' diarrhea, typhoid and *Helicobacter pylori*. Instead, Acambis is now focusing on nine products in late-stage development at its Cambridge, Massachusetts, site. As a result, 40 of the 65 staff—including 25 researchers—will lose their jobs at Acambis' Cambridge, UK, site, leaving the company with a total workforce of about 280. Although Acambis will retain the UK site as its head office, the news is a blow to the UK's struggling biotechnology industry. Genghis Lloyd-Harris, biotech analyst at investment bank Credit Suisse First Boston (London), said the relocation effectively made Acambis into a domestic US company. He noted that US biotech firms in general are more highly valued than their UK counterparts at similar stages of development, so the move could potentially have a "highly positive" effect on Acambis' valuation. In addition, the United States represents by far the biggest market for Acambis' leading vaccines including smallpox and travel vaccines such as dengue fever vaccine. *PM*

Japan opens IP court

Japan is planning to establish a new supreme court for intellectual property (IP) in April 2004, following industry pressure to create an independent body. The new 'IP High Court' is made up of four current IP divisions of the Tokyo High Court. This court will rule on all appealed IP cases, including those in the biotechnology sector, and is expected to speed the trial process and make consistent judgments in case of litigation. Japan's IP trial load for all industry sectors jumped from 470 cases in 1997 to 607 in 2002. With a 55% rise (between 2001 and 2002) of patents filed in the life science sector, the amount of litigation concerning biotech patents has likewise increased. But patent litigation in Japan typically takes two to three years, compared to one year in the US, according to Hiroshi Akimoto, executive director at Takeda Chemical Industries (Tokyo) and chairman of a committee on intellectual property at the Japan Bioindustry Association (Tokyo). Akimoto says Japan's biotech companies would benefit if the country sped up its trial system. But he believes that improvements are still needed and the court should appoint more judges with degrees in technology. *KK*

UK tackles BTWC

The UK's Royal Society (London) has urged governments worldwide to establish an independent body to enforce the Biological and Toxin Weapons Convention (BTWC), which prohibits the use and the production of biological weapons but does not have provisions to ensure compliance. Past efforts to strengthen BTWC have failed. Notably, the US government rejected, in 2001, a draft protocol citing concerns over national security while industry groups lobbied for restricted site visits fearing loss of trade secrets (*Nat. Biotechnol.* **19**, 793, 2001). The Royal Society calls for the creation of a scientific advisory body similar to that supporting the Chemical Weapons Convention, in order to establish a code of conduct to ensure compliance with BTWC. However, such a body may not have enough weight. "To actually strengthen the convention you need something that is legally binding," says Graham Pearson, visiting professor of international security at Bradford University (UK). Gillian Woollett, vice president, Science and Regulatory Affairs at the Biotechnology Industry Organization (Washington), says the increased costs of demonstrating compliance with a code may be substantial and ultimately add to the costs of medicines. A better approach, suggests Pearson, is to extend existing health and safety regulations, which already address the safety of workers and the community, to include transborder safety and thus compliance with the provisions of BTWC. *ED*

News in Brief written by Aaron Bouchie, Emma Dorey, Liz Fletcher, Jeffrey L. Fox, Kim Griggs, Hepeng Jia, Keiko Kandachi, Peter Mitchell, Cormac Sheridan and Aparna Surendran.

Slow GM progress in Africa

In late January, a genetically modified (GM) sweet potato resistant to feathery mottle virus failed its initial field trials in Kenya. The sweet potato was originally licensed from Monsanto (St. Louis, MO, USA) to the Kenya Agricultural Research Institute (Nairobi, Kenya), and now a second-generation strain, resistant to the Kenyan viral isolates, is in development. Florence Wambugu, CEO of the nonprofit organization A Harvest Biotech Foundation International (Nairobi, Kenya), does not view the initial results as a setback, but characterizes the overall effort as an exercise in building GM expertise. Several African countries are beginning to develop their own capabilities in the area in a bid to boost productivity of crops that are specific to their needs (see **Table 1**), but the continent must first tackle political and infrastructure problems before agricultural biotechnology can make a genuine contribution to alleviating poverty and food insecurity there (*Nat. Biotechnol.* **21**, 589, 2003). "The [pests and diseases] are important, but that is not the reason we do not have enough food," says Rudolf Herren, director general of the International Center of Insect Physiology and Ecology (Nairobi, Kenya). *CS*

Table 1 Biotechnology projects targeted to local needs in Africa

Country	Product	Trait
Uganda[1]	Banana	Fungus resistance (black sigatoka) and banana pest resistance (nematodes, weevils)
Kenya[2]	Sweet potato	Virus resistance (feathery mottle virus)
Kenya[2]	Maize	Insect resistance (stem borer)
Egypt[3]	Squash and melon	Virus resistance (zucchini yellow mosaic potyvirus)
Egypt[3]	Potato	Virus resistance (potato virus X, potato virus Y, potato leaf roll virus) and insect resistance (potato tuber moth)
Egypt[3]	Tomato	Virus resistance (tomato yellow leaf curl virus)
Egypt[3]	Faba beans	Virus resistance (faba bean necrotic yellows virus) Fungus resistance (chocolate spot disease)
Egypt[3]	Banana	Virus resistance (banana bunchy top virus, banana-cucumber mosaic cucumovirus)
Egypt[3]	Wheat	Drought & salt stress tolerance
Egypt[3]	Barley	Abiotic stress tolerance
Egypt[3]	Cotton	Insect resistance Heat & salt stress tolerance
Egypt[3]	Maize	Insect resistance (stem borer)

[1]National Agricultural Research Organization, Entebbe; Makere University, Uganda. [2]Kenya Agricultural Research Institute, Nairobi, Kenya. [3]The Agricultural Genetic Engineering Research Institute (AGERI), Giza, Egypt (http://www.ageri.sci.eg/). ***CS***

Aventis takeover may harm biotech

Pharmaceuticals firm Aventis (Strasbourg, France) could be forced to drop its biotech development projects if a €47 ($60) billion hostile takeover bid from French rival Sanofi-Synthélabo (Paris) succeeds. The move would help Sanofi fill its depleted drug portfolio with Aventis' much stronger R&D pipeline. In the past two years, Aventis signed two major deals licensing anti-cancer products from biopharmaceuticals firms Genta (Berkeley Heights, NJ, USA) and Regeneron (Tarrytown, NY, USA) worth $480 million and $510 million, respectively. By contrast, "Sanofi has made very limited investment in human biotechnology in recent years," commented Claude Allary, managing partner of biotech investment advisor Bionest (Paris). "There is a big question mark over Aventis' biotech projects if the deal goes ahead. Sanofi will be very pragmatic about taking control of Aventis' R&D, and biotech may simply not appear on its radar screen." As *Nature Biotechnology* went to press, analysts were predicting that Aventis shareholders would eventually accept Sanofi's offer, although they may hold out for a slightly higher price. There was also speculation that a 'white knight' bidder might emerge—possibly Novartis (Basel). *PM*

Incyte closes databases

Incyte (Wilmington, MA, USA) announced on February 2 that it would lay off 257 staff, finally shutting the door on its gene information service. Demand for subscriptions to Incyte's genomics databases, the firm's main revenue generator, had 'softened' over the past few years largely because of free public data. The company's revenue slid from $219 million during the genomics boom of 2001 to just $47 million during 2003. Genomics companies realized that long-term profits lie in drug or diagnostic development rather than the provision of data, but among its peers, Incyte has been tardy to act (*Nat. Biotechnol.* **19**, 1092–1093, 2001). For example, in 2001 Incyte's closest competitor, Celera Genomics (Rockville, MD, USA), announced it would acquire chemistry company Axys Pharmaceuticals and by late 2002 it had completed the transition to drug discoverer by handing over genomics databases to Applied Biosystems. Incyte did not announce a similar chemistry acquisition (Maxia Pharmaceuticals) until late 2002, but it is swiftly playing catch up: Incyte recently licensed an HIV drug Reverset in phase 2 and has several preclinical drug candidates. And with $294 million in cash and investments still in the bank, Incyte can handle its anticipated drug development costs (~$70 million per annum) for a few years. *LF*

FDA, SEC to share data

Aiming to strengthen a long-standing interagency program, officials at the US Food and Drug Administration (FDA; Rockville, MD, USA) announced on February 5 several measures for supporting the Securities and Exchange Commission (SEC; Washington, DC, USA) when dealing with FDA-regulated firms that issue false and misleading claims. Specified FDA employees will be authorized to share non-public information, such as interim clinical trial results and other proprietary data, with SEC staff without having to seek such authority on a case-by-case basis. "When companies misrepresent the status of the FDA's review of their products, investors can be harmed," says Stephen Cutler, director of the SEC Division of Enforcement. "We are eager to continue working with the FDA to aggressively address such situations…" These measures centralize information exchanges that are "consistent" with current practices. According to a spokesperson, BIO is reviewing the subject matter and will soon complete best practice guidelines for its member companies. *JLF*

Fast track for pandemics vaccines

The European Commission (EC; Brussels) is finalizing plans for a fast-track procedure to license vaccines designed to combat pandemic influenza strains such as avian flu. This could help biotech companies involved in vaccine development reach profitability sooner by bringing some of their products to market more quickly. The EC's Vaccine Expert Group (VEG), composed of experts appointed by the Committee for Proprietary Medicinal Products (CPMP; London), is due this March to consider responses to a draft guideline issued in December 2003. Following its deliberations, the VEG will pass its proposed set of guidelines for marketing authorization applications to the CPMP—which is part of the European Agency for the Evaluation of Medicinal Products (EMEA; London, UK). The draft guideline envisages a two-phased approach to the process. Applicants would first submit a core dossier containing details of validated production processes, testing strategies and relevant preclinical and clinical data. This data would then be supplemented by a so-called 'pandemic application variation,' which could only be prepared once the pandemic reference strain becomes available. The recommended procedure would not be legally binding but EMEA expects applicants to adopt it. "Because of the way [the guidelines] are prepared, they do reflect a certain level of consensus within the community," says EMEA spokesman Martin Harvey Allchurch. *CS*

NASD limits shorting

On January 20, the National Association of Securities Dealers (NASD; Washington, DC, USA), the self-regulatory arm of the US securities industry, eliminated a loophole that allowed brokers to sell a company's shares that never existed. This practice often presented the false appearance of a sell-off and drove the company's share price down. An investor can bet a company's share price will decrease by 'short selling': having a broker borrow shares from a bank, sell them at the current price, buy them back later at a lower price and then return the shares to the lender and pocket the difference (*Nat. Biotechnol.* **21**, 1133, 2003). Although this process is healthy for the market to maintain realistic valuations when hype outpaces a company's fundamental worth, regulatory loopholes have allowed offshore brokers to short sell companies' stock without ever borrowing the shares, a practice called 'naked short selling.' Small companies that are high-risk investments, such as biotech firms, are particularly vulnerable to such a practice. "Naked short selling enables fraudsters to beat up on little companies, which are particularly at risk, by driving down share prices and making it harder for them to raise capital," says Jim DeCosta, author of a forthcoming book on the topic. Now, amendments to NASD Rule 3370 require brokers to deliver the shorted stocks within three business days. *AB*

Cloning conifers

Next June, forestry biotechnology company Trees & Technology (T&T; Whakatane, New Zealand) will plant the first cloned tree of the world's largest conifer cloning program designed to produce about 3 million Monterey pine trees (*Pinus radiata*) cuttings. The clones are created from just 12 trees selected for traits such as stiffness, strength and freedom from distortion. T&T uses propagation technology such as organogenesis and somatic embryogenesis to produce clones on a commercial scale. "In due course [forestry clients] will have vast tracts of these clones and capture [their] additional value," says Andrew Rodwell, CEO at T&T. The advantage of using cloned trees, says Euan Mason, associate professor at the School of Forestry at the University of Canterbury (Christchurch, New Zealand), is predictability [of phenotypic traits] but there are still question marks over issues such as when to choose the clone and whether the desired properties of the clone will endure. "There are risks from having all of one genotype if you get it wrong," says Mason. "If you get it right, then presumably your profits are going to be much higher," he adds. The forecasted demand for timber wood worldwide will reach 1.8 billion cubic meters by 2010, exceeding supply by 23% according to 1998 estimates by the Council of Forest Industries (Vancouver, BC, Canada). *KG*

IPO window sustained

The public markets continue to look favorably on the biotech sector, with three biotech firms completing initial public offerings (IPO) at the beginning of 2004. The biggest success was ophthalmic drug delivery firm Eyetech Pharmaceuticals (New York), which raised $136.5 million on January 30 and whose share price rose nearly 60% to $33 on its first day of trading. The current IPO window began when seven biotech companies completed IPOs between October 8 and November 6 of last year, raising an average of $62.5 million (*Nat. Biotechnol.* **21**, 1413–1414, 2003). The share prices of six of those firms initially dropped, but now five are trading near or above IPO price. Neurology firm Renovis (S. San Francisco, CA, USA) and cancer company GTx (Memphis, TN, USA) completed IPOs too in early February, raising $66 million and $78.3 million, respectively. Renovis's share price rose 35% to $16.25 in its first week of trading, but GTx's dropped 13% to $12.60 in the same time frame. Eric Schmidt, managing director at SG Cowen (New York), says there weren't any IPOs between November 6 and January 30, "because the general market conditions dropped across the board for all industries." *AB*

E&Y focus on innovation

Ernst & Young International (E&Y; New York) surveyed 64 executives within the pharmaceutical and biotechnology industries to determine what policies "would contribute the most to driving innovation." Released on January 22, the results indicate that three of the innovation policy priorities concern the regulatory environment, reimbursement policies and intellectual property, but the priorities of Europe and the US differ. For example, European executives are more concerned with harmonizing regulations and enhancing market-based pricing policies to alleviate government-imposed price caps on drugs, but US executives view policies on patent exclusivity as the most important. Carolyn Buck-Luce, lead pharmaceutical partner at E&Y and author of the survey, believes that biotech companies would seek improved IP protection for their innovative "production processes." Meanwhile, "regulatory harmonization in the EU will take a long time," says Buck-Luce, but she points to Ireland as an example of a nation that has implemented its own policies to encourage innovation. *AB*

New US cell therapy rule

The US Food and Drug Administration (FDA; Rockville, MD, USA) in January implemented regulations to promote safety for companies that handle reproductive tissue and human cellular products, including stem cells derived from various blood sources such as umbilical cord blood. Previously, the FDA only regulated 'traditional' tissues such as bone, ligaments, skin and tendons. Now, all tissue banks—there are 150–200 of them, according to the American Association of Tissue Banks (McLean, VA, USA)—will have to register with the agency and list each of their cell or tissue products. Robert Hariri, president of the cellular therapeutics division at Celgene (Warren, NJ, USA), welcomes the regulations because cell and tissue products are becoming more common sources of therapeutics. "The absence of these high standards is a recipe for disaster," he says. "Nothing would be a greater disservice to the public than these revolutionary therapies being held back because of a clinical investigation failure due to a poor quality product." In addition, the FDA is looking into two proposed tissue regulations: one that would create donor suitability standards and another that would require manufacturers to follow current good tissue practices. The agency also announced that heart valves and dura mater, currently classified as devices, would be considered tissues once the tissue regulatory framework is completed. *AS*

Carl Feldbaum to retire later this year

After 11 years as the only president of the Biotechnology Industry Organization (BIO; Washington), Carl Feldbaum announced his plans to leave this post sometime later this year once his successor is found. Feldbaum, an attorney and former special prosecutor as well as chief of staff for Republican Senator Arlen Specter (Pennsylvania), has presided over BIO during a period of rapid growth for the organization as well as the industry it represents. Indeed, BIO grew from the merger of two squabbling predecessor associations with barely more than a dozen full-time employees into a well-heeled, widely recognized organization with a staff of more than 100 and a membership now exceeding 1,000 companies, academic institutions and biotechnology centers. At the outset, Feldbaum insisted on BIO maintaining a focused, nonpartisan agenda that led to some noteworthy early successes—for example, BIO was instrumental in blocking efforts by the Clinton administration to impose price controls on new therapeutics. Those successes, in turn, enabled Feldbaum to expand BIO's activities into areas such as bioethics, responding to the needs of member companies that found themselves embroiled in national debates beyond ordinary matters of federal regulation. BIO Chairman, Richard Pops, who is also CEO of Alkermes (Cambridge, MA, USA), calls Feldbaum a "pioneer" who "has had a profound impact on the evolution of this young industry." *JLF*

Selected research collaborations

Company 1	Company 2	$ (millions)	Details
Jerini AG (Berlin, Germany)	Merck KgaA (Darmstadt, Germany)	62.5	A collaboration to develop Jerini's small molecule inhibitors against undisclosed cancer targets. Jerini will receive an upfront payment and is eligible for milestones and royalties. Jerini could also receive over $62.5 million if a product is approved, leaving Merck with worldwide rights for all indications in cancer.
Aventis Pasteur (Lyons, France)	Crucell (Leiden, The Netherlands)	38	An agreement to develop influenza vaccine products. Crucell will provide a cell line that it developed for manufacturing biological products, such as vaccines. Crucell is eligible for research funding, milestones and royalties totaling $38 million. Aventis is eligible for royalties on sales of developed vaccines in Japan, where rights are reserved to Crucell.
Iconix Pharmaceuticals (Mountain View, CA, USA)	Bristol-Myers Squibb (BMS; Princeton, NJ, USA)	24	An agreement to use Iconix's technology to select candidate drugs and improve knowledge of the safety of BMS's compounds. BMS will access Iconix's chemogenomics technology to get information on the genomic effects of drugs and chemical treatments, and its library of genes, which serve as genomic biomarkers used to predict the side effects and toxicology of drug candidates.
Xenoport (Santa Clara, CA, USA)	Pfizer (New York)	*	A collaboration to develop technologies that improve access of drugs to targets in the brain. Xenoport will provide parts of its medicinal chemistry technology to design drugs that engage active transport systems in the brain. Pfizer will provide research expertise and funding. Both companies will share the use of technologies developed.
Beyond Genomics (Waltham, MA, USA)	GlaxoSmithKline (GSK; London)	*	A partnership to identify new biomarkers of metabolic disorders and drug response. Beyond Genomics will provide its systems biology technologies to GSK's continuing study of disease and drug response in several metabolic diseases. Beyond Genomics will receive an upfront fee and is eligible for additional payments.
IntegraGen (Evry, France)	Aventis (Strasbourg, France)	*	A deal to discover genes associated with schizophrenia. IntegraGen will provide its profiling technology to perform a genome-wide linkage analysis on a collection of DNA from familial-related schizophrenia patients characterized by the Aventis Human Genetics Center (Evry, France).

*Financial details not disclosed. ***AS***